DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Onux Medical, Inc.
Mr. John Rice
Vice President of Engineering
5 Merrill Drive
Hampton, NH 03842

JUL 27 2015

Re: K010620
Trade/Device Name: Endoscopic Staple Removal Instrument
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated (Date on orig SE ltr): February 27, 2001
Received (Date on orig SE ltr): March 1, 2001

Dear Mr. Rice,

This letter corrects our substantially equivalent letter of May 17, 2001.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K010620

Statement of Indications for Use

INDICATIONS

The Salute staple removal instrument is a re-useable instrument intended for laparoscopic or open removal of Salute staples.

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010620

K010620

MAY 1 7 2001

510(k) Summary

2/27/2001

Onux Medical, Inc., Contact Person:	John Rice
Trade or Proprietary Name:	None established
Common or Usual Name:	Endoscopic staple removal instrument
Classification Name:	Endoscope and/or Accessory

Devices to Which Equivalence is Claimed
The Salute staple removal instrument is substantially equivalent to the Ethicon Endopath™ ES Endoscopic Staple Extractor.

Description of Subject Device
The subject device is a manual instrument for endoscopic or open surgical procedures. It employs a trigger handle design with an actuation lever and 5mm shaft. A rod at the end of the shaft engages the underside of the staple and pulls it inside the shaft when the lever is actuated. When the lever is released, the staple is release from within the device. The instrument is re-useable and is sterilized by steam autoclave.

Intended Use of Subject Device
Both the Salute staple removal instrument and the Ethicon Endopath ES Endoscopic Staple Extractor are intended for laparoscopic or open removal of staples.

Comparison of Technical Aspects
Both the Salute staple removal instrument and the Endopath ES Staple Extractor are manual re-useable instruments for removing staples in either an open or laparoscopic surgical setting. They both engage the underside of the staple at the distal end of the device shaft. Both have levers that actuate the un-bending of the staple. While the lever is kept closed, the extracted staple is held by the device for removal to outside the surgical area. Releasing the lever expels the staple from the device shaft.